

CLAIM SET AS AMENDED

---

1-82. (canceled).

83. (new) A recombinant virus vector that is a lentivirus vector, adenovirus vector, adeno-associated virus vector or replication deficient adeno-virus vector comprising two terminal repeat sequences and a packaging signal of said virus, and a promoter nucleic acid fragment of a mammalian myosin light chain-2 gene,

61 wherein the promoter nucleic acid fragment is operatively linked to the terminal repeat sequences and packaging signal of said virus and is effective for cardiac tissue specific expression of the nucleic acid sequence to be expressed under conditions of somatic gene transfer.

84. (new) The vector of claim 83, wherein the promoter nucleic acid fragment comprises nucleotides of approximately residue -19 to approximately residue -2700, with respect to the transcription starting point, of the mammalian myosin light chain-2 gene.

85. (new) A vector comprising the vector pADRSV $\beta$ gal having a DNA fragment comprising nucleotides 1661 to 2405 of SEQ ID

NO:1 inserted at the Pvu II restriction enzyme site adjacent to the 3' end of the 1.3 m.u. region of the Ad5 genome.

86. (new) The vector according to claim 83, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

87. The vector according to claim 84, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

88. (new) The vector of any one of claims 83 to 87, further comprising a desired nucleic acid to be expressed that is operatively linked to said promoter.

89. (new) The vector according to claim 88, wherein the nucleic acid sequence to be expressed encodes a proteinaceous gene product.

90. (new) The vector according to claim 89, wherein the proteinaceous gene product is selected from a dystrophin, a  $\beta$  adrenergic receptor or a nitric oxide synthetase.

92. (new) The vector of claim 91, further comprising a CSS element consisting of nucleotides of a mammalian myosin light chain - 2 promoter corresponding to nucleotides 682 to 724 of SEQ ID NO: 1 that is operatively linked to the 3' end of the promoter nucleic acid fragment.

93. (new) The vector according to claim 91, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

94. (new) The vector according to claim 92, wherein the virus vector is a replication deficient adenovirus vector comprising two inverted terminal repeat sequences (ITR) of the adenovirus.

95. (new) The vector of any one of claims 91 to 94, further comprising a desired nucleic acid to be expressed that is operatively linked to said promoter.

96. (new) The vector according to claim 95, wherein the nucleic acid sequence to be expressed encodes a proteinaceous gene product.

97. (new) The recombinant virus vector according to claim 96, wherein the proteinaceous gene product is selected from a dystrophin, a  $\beta$  adrenergic receptor or a nitric oxide synthetase.

98. (new) A composition comprising the vector of claim 88, complexed with liposomes.

99. (new) A composition comprising the vector of claim 89, complexed with liposomes.

100. (new) A composition comprising the vector of claim 90, complexed with liposomes.

101. (new) A composition comprising the vector of claim 95, complexed with liposomes.

102. (new) A composition comprising the vector of claim 96, complexed with liposomes.

103. (new) A composition comprising the vector of claim 97, complexed with liposomes.

~~104~~. (new) A composition comprising the vector of claim 88 and a pharmaceutically acceptable carrier.

~~105~~. (new) A composition comprising the recombinant virus vector of claim 89 and a pharmaceutically acceptable carrier.

~~106~~. (new) A composition comprising the recombinant virus vector of claim 90 and a pharmaceutically acceptable carrier.

~~107~~. (new) A composition comprising the recombinant virus vector of claim 95 and a pharmaceutically acceptable carrier.

~~108~~. (new) A composition comprising the recombinant virus vector of claim 96 and a pharmaceutically acceptable carrier.

~~109~~. (new) A composition comprising the recombinant virus vector of claim 97 and a pharmaceutically acceptable carrier.

~~110~~. (new) A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 88, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby

delivering the desired gene to the cardiac muscle cells of the subject.

111. (new) A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 89, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

112. (new) A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 90, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

113. (new) A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 95, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby

91. (new) A recombinant virus vector that is a lentivirus vector, adenovirus vector, adeno-associated virus vector or replication defective adenovirus vector comprising two repeat sequences and a packaging signal of said virus, and a promoter nucleic acid fragment comprising operatively linked, in the order stated from 5' to 3', the regulatory elements:

HF 1a and 1b consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2340 to 2361 of SEQ ID NO:1;

MLE1 consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2229 to 2241 of SEQ ID NO: 1; and

HF 3 consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2207 to 2219 of SEQ ID NO: 1; an E box element consisting of nucleotides 2328 to 2333 of SEQ ID NO: 1; and optionally

an HF 2 element consisting of nucleotides of a mammalian mlc2 promoter corresponding to nucleotides 2271 to 2289 of SEQ ID NO: 1;

wherein the promoter nucleic acid fragment is operatively linked to the two terminal repeat sequences and the packaging signal of said vector and is effective for cardiac tissue specific expression of the nucleic acid sequence to be expressed under conditions of somatic gene transfer.

delivering the desired gene to the cardiac muscle cells of the subject.

114. (new) A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 96, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

115. (new) A method for delivery of a desired gene to cardiac muscle cells of a subject, which method comprises administering a recombinant virus vector according to claim 97, optionally complexed with liposomes, to cardiac tissue, heart blood vessels or the heart cavity of a subject, thereby delivering the desired gene to the cardiac muscle cells of the subject.

116. (new) The method of claim 110, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure,



atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

117. (new) The method of claim 111, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

61  
118. (new) The method of claim 112, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

119. (new) The method of claim 113, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

120. (new) The method of claim 114, wherein the subject presents a heart disease selected from the group consisting of a heart insufficiency, dilative or hypertrophic cardiomyopathy, dystrophinopathy, vessel disorder, high blood pressure, atherosclerosis, stenosis of a blood vessel, or restenosis of a blood vessel.

---